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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,925	03/04/2002	Stefano Dall'Oglio	205,546	6677
7590 03/02/2004			EXAMINER	
ABELMAN, FRAYNE & SCHWAB			BEISNER, WILLIAM H	
Attorneys at Law 150 East 42nd Street			ART UNIT	PAPER NUMBER
New York, NY 10017-5612			1744	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

4	Application No.	Applicant(s)	Λ		
	10/090,925	DALL'OGLIO, STEFANO	10		
Office Action Summary	Examiner	Art Unit	$D^{\circ}$		
Ź	William H. Beisner	1744	***		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	i6(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	nely filed s will be considered timely. the mailing date of this communication O (35 U.S.C. § 133).	1.		
Status					
1) Responsive to communication(s) filed on	'				
2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This action is non-final.  3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
Disposition of Claims					
4) Claim(s) 1-12 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-12</u> is/are rejected.		•			
7) Claim(s) is/are objected to.	r alastian raquiromant				
8) Claim(s) are subject to restriction and/or	election requirement.				
Application Papers					
9) The specification is objected to by the Examine	· ·				
10)⊠ The drawing(s) filed on 04 March 2002 is/are: a	a) accepted or b) objected to	by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☑ None of:  1. ☑ Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)	<b></b>				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) La Interview Summary Paper No(s)/Mail Da				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) 🔲 Notice of Informal Pa	atent Application (PTO-152)			
Paper No(s)/Mail Date	6)				

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#### **DETAILED ACTION**

## **Priority**

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 02 March 2001. It is noted, however, that applicant has not filed a certified copy of the Italian application as required by 35 U.S.C. 119(b).

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 2 rejected under 35 U.S.C. 102(b) as being anticipated by Southgate et al.(US 5,863,502).

The reference of Southgate et al. discloses a device that includes: a body of plastic material (105) including a reaction chamber (340) in communication with a pierceable and tight re-sealable septum (which can be accessed from outside by means of a syringe; an optically transparent and liquid tight element enclosing the reaction chamber; one or more deformable tanks containing appropriate reagents for measurement; a deformable tank intended to contain discharge liquids; all said tanks being individually connected to the reaction chamber by means of a network of micro-channels provided in the unit body in order to guarantee tightness of the unit against possible spilling out of liquids.

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## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. Claims 2, 4, 6, 8, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southgate et al.(US 5,863,801) in view of Southgate et al.(US 5,863,502).

With respect to claim 2, the reference of Southgate et al. ('801) discloses a device that includes: a body of plastic material (105) including a reaction chamber (1108) in communication with a pierceable and tight re-sealable septum (1104) which can be accessed from outside by means of a syringe; a liquid-tight element enclosing the reaction chamber (films 110,120); one or more deformable tanks containing appropriate reagents for measurement (1113-1116); a deformable tank (1110) intended to contain discharge liquids; all said tanks being individually connected to the reaction chamber by means of a network of micro-channels (See Figure 9)

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provided in the unit body in order to guarantee tightness of the unit against possible spilling out of liquids.

While the reference of Southgate et al. ('801) discloses the use of films (110,120) to seal the reaction chamber (1108), the reference is silent as to whether or not the films are optically transparent.

The reference of Southgate et al. ('502) discloses a reaction cassette device similar to that of the primary reference. The reference of Southgate et al. ('502) discloses that it is known in the art to provide the films as transparent members so as to monitor the contents of the reaction chamber (See column 23, line 29, to column 24, line 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the primary reference with transparent films as suggested by the reference of Southgate et al. ('502) for the known and expected result of optically monitoring the contents of the reaction chamber.

With respect to claims 4 and 6, whether both films are transparent or only one, the reference of Southgate et al. ('502) discloses that the transparency of the films is based on the intended optical system employed to monitor the contents of the reaction chamber (See column 23, lines 38-46).

With respect to claims 8 and 10, the deformable tanks are delimited by deformable membranes (110) and the discharge tank is capable of being filled by hydraulic pressure produced when filling the reaction chamber.

With respect to claim 12, based on the dimensions disclosed by Southgate et al.('801) (See column 12, lines 61-67), the reaction chamber of the reference is within the claimed range.

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7. Claims 1, 3, 5, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southgate et al.(US 5,863,801) in view of Southgate et al.(US 5,863,502) and Pourahmadi et al.(US 6,440,725).

The combination of the references of Southgate et al. has been discussed above.

Claim 1 differs by reciting that the reaction chamber includes a filter for collection of microbes present in a fluid.

The reference of Pourahmadi et al. discloses that it is known in the art to provide a reaction chamber or lysing chamber for capturing microbes contained in a fluid sample (See column 9, lines 10-13).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the lysing chamber (1108) of the reference Southgate et al. ('801) with a filter as suggested by the reference of Pourahmadi et al. for the known and expected result of providing a means recognized in the art for use in a lysing chamber for the capture of microbes contained in a fluid sample.

With respect to the limitation in claim 1 that the optically transparent and liquid-tight element is movable and capable of enclosing said reaction chamber or exposing it to a liquid or gas flow, the upper and lower films (110,120) are deformable and therefore are movable with respect to body (105). Also, the films enclose the reaction chamber. While the films are positioned over the chamber, fluid sample is able to contact the chamber.

The limitations of claims 3, 5, 7, 9 and 11 are met for the same reasons as set forth with respect to the combination of the references of Southgate et al. set forth above.

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#### Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Apicella (US 4,859,421) is cited as prior art that discloses the use of a movable element (27) that seals reaction chamber (15). This reference does not disclose the use of a filter positioned within the reaction chamber.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner Primary Examiner Art Unit 1744

**WHB**